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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Dan E. Fischer

7678.811

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22913

7590

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EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,503	Applicant(s) FISCHER, DAN E.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-15 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,14,15 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3rd 2008 has been entered.

Claims 11-13 (group II) remain withdrawn from further consideration.

Claims 4, 5 and 16-27 have been canceled by applicant's previous amendments.

Claims 1-3, 6-10, 14, 15 and 28-33 (as currently amended) are examined on their merits in this office action.

Claim Suggestions

Claim 7, as currently amended, has minor informality in the form of a misspelled limitation in line 2. The term "non-elongate" has been misspelled as "non-elangate". Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7 (as currently amended) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The insertion of limitation "**non-elongate**, pillow like configuration" in instant claim 7 (see also claim suggestions above), as currently recited, does not have support in the as-filed specification. The insertion of this limitation represents **a new concept** because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the "non-elongated, pillow like" configuration of the "moisture activated implant device" as currently presented by applicants. There is only one exemplification depicted in the form of figure 1B, but it fails to support all forms of "non-elongated, pillow like" configurations, as currently presented by applicants in this new concept. Moreover, applicant's response (see remarks, page 6, in particular) fails to provide the basis for this limitation as currently recited in the claim. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of the limitation "**non-elongate**, pillow like configuration" is deemed as an insertion of a **new matter**. Appropriate correction is required.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3, 6, 7, 14, 15 and 28-33 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al (US 4,863,472; [D]) taken with Silverberg (US 4,755,184; [E]) and Kenyon et al (US 2,423,707; [A]).

Claims (as currently amended) are generally directed to "A moisture activated implant device for placement into a void space within a bone, adhesion to bone tissue, and promoting bone growth in the void space, comprising:

a dry covering comprised of a water absorbing gelatinizable material that defines an enclosed space and which becomes sticky and gelatinous upon contact with water so as to render it adhesive to bone tissue, wherein the dry covering consists essentially of oxidized cellulose, and

a bone growth promoting material, disposed within the enclosed space defined by the dry covering, selected from the group consisting of hydroxyapatite, beta-tricalcium phosphate, purified coral shell, freeze dried natural bone powder, freeze dried natural bone particles, demineralized natural bone powder, demineralized natural bone particles, demineralized natural bone shards, demineralized natural bone fragments, and combinations thereof,

wherein the dry covering encapsulates and retains the bone growth promoting material within the enclosed space prior to use." (see instant claims 1-3, 6, 7, 14, and 15; that include a method of using said implant device for promoting bone growth); and wherein the implant device comprises the bone growth promoting material in granular or powder form, and a thickener dispersed among said bone growth promoting material. (see specific recitations of claims 28-33)

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Tormala et al [D] disclose an implant device comprising “water absorbing gelatinizable material” (a supporting structure suitable to work as a covering/encasing made of materials such as polyglycolide, **cellulose derivatives** or cross-linked **collagen** derivatives such as cat gut/**Katgut**; see Tormala et al, abstract; figures 1-2; columns 3-4; and column 4, lines 17-25, in particular) and a “bone growth promoting material” contained within said gelatinizable material (see Tormala et al, abstract and claims, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is **hydroxyapatite** powder; see column 8, example 2, in particular), wherein the implant device has an elongated sausage-like or pillow like configuration (undefined limitations, “sausage-like” or “pillow-like” configurations; see Tormala et al, figures 1-3 and column 5, 3rd paragraph, in particular), and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Tormala et al, columns 5-6, in particular). In addition, Tormala et al disclose the fact that one can use or admix resorbable fibers, or polymer to bind (to work as a glue, i.e. used as a **thickener** that can form viscous gel upon contact with water) the bone graft particles together, if used as an additional inner resorbable supporting structure of the powder phase (see column 3, lines 1-2; column 4, last paragraph; and claim 9, in particular). Also disclosed in Tormala et al is the fact that the supporting structure (i.e. the covering) can be made of any shape or size (such as a bag or a flat tube; see abstract, column 6, lines 57-64, in particular) and the

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covering can be constructed in the form of a **woven or knitted** fibers (see column 5, lines 36-38, and claim 10, in particular).

Silverberg [E] discloses an implant device comprising “water absorbing gelatinizable material” (suitable to work as a covering material such as a **casing** made from polyglycolide in the form of a mesh, or **collagen or cellulose**; see abstract, summary of the invention, column 3, lines 31-55, and claims, in particular) and a “bone growth promoting material” contained within said gelatinizable material (such as hydroxyapatite; see examples, column 4-5, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is hydroxyapatite powder, wherein the implant device has **an elongated sausage-like configuration** (see figure 1, in particular) and is gas sterilized prior to surgical applications (see column 5, 1st paragraph, in particular); and teaches a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Silverberg, column 4 and figure 3-5, in particular).

However, the inventions of Silverberg or Tormala et al do not explicitly teach (although, suggest the generic materials such as collagen and cellulose, and derivatives thereof; see discussions above) the “dry covering” to be made of a water absorbing material that becomes sticky and gelatinous upon contact with water (i.e. moisture activated), and wherein the dry covering **consists essentially of oxidized cellulose**.

Kenyon et al [A] disclose a **gelatinizable gauze** (i.e. a surgical fabric or sponge made of **oxidized cellulose**; see columns 1-2, and claims in particular) to be used as a dressing material on wounds, cuts and the like, wherein the gauze can be resorbable

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(see column 1, last paragraph, in particular) *in vivo*, or non-resorbable (depending on the amount or extent of oxidization using NO₂ and a halogenated hydrocarbon; see column 2, 2nd paragraph, and examples 1 and 2, in particular), and thus, can be used as a hemostat or as a dressing (in woven or knitted forms; see figures 1-2) for the treatment of the wound.

Therefore, it would have been obvious to a person of ordinary skill in the clinical art to modify the inventions of Tormala et al or Silverberg such that the covering used is made of a water absorbable gelatinizable material such as oxidized cellulose (i.e. a gelatinizable gauze made of oxidized cellulose) which is explicitly taught by Kenyon et al for the benefits of having both resorbable and/or non-resorbable properties of the oxidized cellulose material used in the form of a woven or knitted material. Thus, an artisan of ordinary skill in the medical art would have been motivated and have had a reasonable expectation of success in substituting the “dry covering” disclosed by Tormala et al or Silverberg with the material (i.e. a functional equivalent, such as cellulose derivatives including “oxidized cellulose” (that are known to be gelatinizable upon contact with water or other aqueous materials such as body fluids, and are known to be bio-resorbable), and which have been explicitly taught by Kenyon et al for the treatment of wounds that produce bleeding (such as during the removal and filling of tooth, voids, etc.).

2. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al (US 4,863,472; [D]) taken with Silverberg (US 4,755,184; [E]) and Kenyon

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et al (US 2,423,707; [A]) as applied to claims 1-3, 6, 7, 14, 15 and 28-33 above, and further in view of Levy (US 5,292,253; [A]) and Vyakarnam et al (US 6,306,424 B1; [F]).

Claims 8-10 are directed to the implant device further comprising "moisture-resistant packaging", or further comprises an adhesive dispersed with the bone growth promoting material, wherein the adhesive comprises at least one of "fibrin powder" or "chopped adhesive gauze".

The detailed teachings of Tormala et al, Silverberg and Kenyon et al have been discussed above, and are further relied upon in the same manner herein.

However, an implant device further comprising an adhesive such as **fibrin powder**; or an implant device, which is stored within **moisture-resistant packaging** is not explicitly disclosed by the referenced inventions of Tormala et al taken with Silverberg, and Kenyon et al.

Levy [A] explicitly discloses the use of **fibrin** with or without collagen (see column 3, lines 24-29, and claims, in particular) to form a protein gel that can be combined with calcium-containing materials such as hydroxyapatite and/or calcium phosphate to prepare an implant used for filling the void or defects for the repair of tooth and bone tissues.

Vyakarnam et al [F] disclose the routine practice of packaging implant materials (i.e. sensitive biological materials) after sterilization in an appropriate sterilized, **moisture-resistant package** for shipment and use in hospitals and other health care facilities (see column 19, 3rd paragraph, in particular).

Therefore, given the detailed disclosures of the components and the structure of the implant device (as claimed in the instant application) in the above cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the implant device taught by Tormala et al (taken with the disclosure of Silverberg and Kenyon et al) such that it further comprises an adhesive

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such as fibrin, and is stored within a moisture-resistant packaging as explicitly suggested and demonstrated by the disclosures of Levy and Vyakarnam et al with a reasonable expectation of success in order to provide a gelling component or a glue in the composition (in order to adhere to the bone at the site of implantation or filling) as well as to avoid contamination of the implant device during transport and storage (both these limitations are deemed to be routinely practiced in the implantation art).

Therefore, the invention as claimed fails to distinguish itself over the combined teachings of the cited prior art references of record.

Thus, the entire invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments filed on September 3rd 2008 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record:

Applicant seems to argue individually against the cited prior art references relied upon in the 103(a) rejection of record (see remarks, pages 7-10, in particular). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant seems to be arguing that the teachings of Tormala et al can not be combined with the disclosure of Silverberg and Kenyon et al because Tormala et al teaches away from the invention as claimed as it does not disclose an implant device that is completely encapsulated by the dry covering made of material (i.e. consisting essentially of oxidized cellulose) that reacts with water to form a sticky, gelatinous material. It is noted that Tormala et al teaches an implant device that comprises bone growth material and a dry covering or encasing that is made of bio- resorbable material and can be made in various shapes and structural forms (see Tormala et al, column 2, 3rd paragraph, and column 4, 2nd paragraph, and column 6, 5th paragraph, in particular), and suggests the use of cellulose derivatives for such encasings that can be made for use in filling voids or teeth gaps in patients in need thereof (i.e. for promoting bone growth). When taken with the teachings of Silverberg and Kenyon et al for encasing made of materials such as "oxidized cellulose" that have same functional properties as currently claimed by applicants, and that can be suitably used for the same purposes for the repair and promotion of bone growth, or for filling void or defect resulting from removal of tooth, the invention as claimed in instant claim 1 would be clearly obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

It is to be noted that applicant has failed to disclose the chemical identity (i.e. the oxidation status, or chemical structure, etc.) of the specific oxidized cellulose derivative used in the instant invention as claimed and the functional properties of which is being

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argued. In the absence of a clear and full disclosure of the material used for making the dry covering for the claimed implant, the cited prior art disclosures that meet all the limitation of the components used for making and using such an implant (for the same purposes as claimed) are deemed relevant and an artisan of ordinary skill in the art would have had strong motivation to use oxidized cellulose for its bio-resorbable and other beneficial properties that are intrinsic to the encasing made from such a material with a reasonable expectation of success.

The argument that Kenyon et al has "*nothing to do with repairing bone defects but only the stoppage of bleeding*" (see remarks, page 9, 3rd and 4th paragraphs) is not found to be persuasive because the references can be combined in the prior art for reasons other than applicant's purposes. Moreover, stoppage of bleeding is pertinent to applicant's invention as claimed as it does intend to fill the void after removal of tooth (see process claims 14 and 15, in particular), and it does intend to use a thickener such as gelatinous collagenous material which are well known in the art and has been disclosed by the cited references of record (see disclosures of Levy and Kenyon et al above) for the same purposes. The argument regarding the shape and sizes of the claimed implant device and its configurations (see instant claims 7; "non-elongate" pillow like configuration) is not found to be persuasive because Silverberg explicitly discloses the sausage-shaped implant with its encasing, and does suggest the fact that an artisan of ordinary skill in the art would be easily able to make an implant that "may be of varying length and diameter depending upon its intended use" (see column 4, lines 1-2). The cited reference of Vyakarnam et al has been relied upon to show that

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the use of “moisture-resistant packaging” for transport and storage of sterile biological implants is well known in the art and an artisan of ordinary skill in the clinical art would have been motivated to use such a packaging for the storage of sensitive implant device as disclosed by the combined teachings of Tormala et al when taken with Silverberg and Kenyon et al.

The arguments that the limitations of claims 28-33 with reference to the use of thickener with the implant device as claimed is not disclosed by the cited references of record, is not found to be persuasive because the cited prior art of Levy explicitly discloses “biocompatible gelatinous collagen material” such as fibrin and/or collagen containing protein gel that can be used as a binder/thickener to fill a gap along with a bone growth promoting material such as calcium-containing substances, for example calcium phosphate or hydroxyapatite (see Levy, columns 1-2 and claims, in particular) while repairing tooth and/or bone tissue. Since, the cited prior art references of record disclose all the limitations of the invention as claimed, and since the disclosure is deemed pertinent to the implant device comprising a dry covering made essentially of oxidized cellulose that can house bone growth promoting material with or without a thickener, in the absence of any evidence to the contrary, the instant invention as claimed (i.e. an implant device and it method of use) is deemed obvious in view of the cited references of record. The rejection of record is therefore, properly made and maintained.

Conclusion

NO claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/
Examiner, Art Unit 1657